

EXHIBIT 60

From: Hansen, Gary
To: Woodwick-Sides, Teri; Stender, Jana; Rock, John
Sent: 3/17/2011 10:21:44 PM
Subject: FW: A&A Decision for MS#: AA-D-11-00065

See below for Dan's suggestions about a new study. He contends that engineering particulate studies are still open to question, and that airborne bacterial sampling is required to make the case. Let's discuss.

Gary

From: Daniel Sessler [mailto:ds@or.org]
Sent: Saturday, March 05, 2011 2:46 PM
To: Hansen, Gary
Subject: FW: A&A Decision for MS#: AA-D-11-00065

Hi Gary,

In case you don't already have them, the reviews for our Laminar Flow manuscript are below. Presumably it will be accepted after suitable revision. I'll work with Russ on it. Congratulations!

One of the reviewer's comments strikes me though: "The authors effectively demonstrate that forced air warming does not impair the effectiveness of laminar flow and would not prevent the laminar flow from reducing the risk of infection, if laminar flow is truly effective in reducing infection. The 2 specific paragraphs in question relate to a second but separate concern with forced air warming- that it has been postulated that forced air warmers may have the potential to increase bacterial counts at the site of surgery. The current study does not study bacterial counts, only the effect of forced air on laminar flow effectiveness. In the discussion (paragraph 3, page 15), the authors correlate their results with studies that demonstrate no increase in bacterial counts and imply that their data supports similar results. Since particles of a synthetic oil, not bacterial counts were measured, the authors should not imply that their data is consistent with studies showing no increase in bacterial counts." We'll probably eventually have to deal with bacteria.

Regards, Dan.

From: Steven Shafer <editor@anesthesia-analgesia.org>
Date: 23 Feb 2011 19:02:33 -0500
To: Russell Olmsted <olmstedr@trinity-health.org>
Subject: A&A Decision for MS#: AA-D-11-00065

CC: dwayne.westenskow@hsc.utah.edu

Feb 23, 2011

Mr. Russell Olmsted
St. Joseph Mercy Health System
Infection Prevention & Control Services

RE: MS#: AA-D-11-00065 "Forced-Air Warming Does Not Worsen Air Quality in Laminar flow Operating Rooms"

Dear Mr. Olmsted:

Thank you for submitting your manuscript "Forced-Air Warming Does Not Worsen Air Quality in Laminar flow Operating Rooms" to Anesthesia & Analgesia for consideration. Your manuscript has been reviewed by our editorial board and outside experts. Based on their reviews and my own reading of your manuscript, I am happy to provisionally accept your manuscript for publication in Anesthesia & Analgesia, pending an adequate response to the issues below.

Please revise your paper as guided by the reviewers' suggestions and provide a point-by-point description of how you responded to their suggestions and concerns. Submit your revision via Editorial Manager by logging in to your author account and clicking the link "Submissions Needing Revision." Be sure you have pasted your response to the reviewers into the appropriate box in the online resubmission form. Please see the "Checklist for Revised Manuscripts" below for more information.

Your revision must be returned to us in 3 months. Please advise if you need more time to complete your revision.

Your revised manuscript may be returned to the reviewers to assess whether you have addressed their concerns.

Thank you again for submitting your manuscript to Anesthesia & Analgesia. I look forward to your revision, as well as future submissions from you and your colleagues.

Sincerely,

Dwayne Westenskow
Section Editor, Technology, Computing, and Simulation
Anesthesia & Analgesia

cc: Dr. Steve Shafer

CHECKLIST FOR REVISED MANUSCRIPTS

RESUBMISSION:

Please follow the specific instructions in your letter from the section editor about resubmission and submit your revision to Editorial Manager (<http://www.editorialmanager.com/aa>)

RESPONSES TO REVIEWERS:

Please copy and paste your point-by-point responses to reviewers in the "Respond to Reviewers" box in Editorial Manager or attach a Word file with your manuscript file.

FORMATTING REMINDERS:

SHORT TITLE (to be used in the short table of contents of the journal):

It should be no more than 60 characters (including letters and spaces) placed at the bottom of the title page and identified.

ABBREVIATIONS:

At first mention of terminology in the abstract, text, each figure legend, and each table, spell out in full and follow immediately with the abbreviation (enclosed within parentheses). Use abbreviations consistently; do not revert to the spelled-out term. Abbreviations can make text very difficult to read, particularly if they are idiosyncratic to the manuscript. Do not create new or unusual abbreviations.

ABSTRACT:

See our Guide for Authors for Abstract requirements: <http://www.aaeditor.org/GuideforAuthors.pdf>

FIGURES and TABLES:

All figures and tables must have legends. Abbreviations in every figure and table and their legends should be defined. Please also include all figures and tables with each revision, even if they were not revised.

IRB APPROVAL AND PATIENT CONSENT:

IRB permission and patient consent should be clearly stated at the beginning of the Methods section.

REFERENCES:

References must be verified by the author(s) against the original documents, and the entire list must be checked for duplication. References should be in A&A style. Abstracts >3 years should be footnoted and not listed in the references. To facilitate editing, double-space between every line of the references and between each reference.

1. Standard journal articles (List all the authors): Dalal PG, Murray D, Cox T, McAllister J, Snider R. Sedation and anesthesia protocols used for magnetic resonance imaging studies in infants: provider and pharmacologic considerations. *Anesth Analg* 2006;103:863-8
 2. Personal author(s) of books and monographs: Zar JH. *Biostatistical Analysis*. 3rd ed. Upper Saddle River, NJ: Prentice-Hall, 1996
 3. Chapter in a book: Eger EI II. Uptake and distribution. In: Miller RD, ed. *Miller's Anesthesia*. 6th ed. Philadelphia: Elsevier Churchill Livingstone, 2005:131-53
 4. Published proceedings paper: DuPont B. Bone marrow transplantation in severe combined immunodeficiency with a paper unrelated MLC compatible donor. In: White HJ, Smith R, eds. *Proceedings of the third annual meeting of the International Society for Experimental Hematology*. Houston: International Society for Experimental Hematology, 1974:44-6
 5. Website: Do not use as a reference. May be used as a footnote (3 or fewer) listing the URL and the date it was last accessed by the author, e.g., NIH Request for Applications. Available at: <http://grants.nih.gov/grants/guide/rfa-files/RFA-HL-08-005.html>. Accessed May 6, 2010.
- For 4 or more websites, please create a table and number each listing. In the text, site the table and number, e.g., "Table 1, Ref. 3."

Reviewer #1: The paper is well written and it demonstrates a well written and good organized concept for studying the problem of particle distribution in the operation room and the old discussion of warming patients and producing turbulences and potential contamination in an laminar flow setup. I have only one special comment that can improve the paper. I think either Figure one or two could be sufficient and the demonstration of Figure 5 a-F will probably poor in printing. probably this last figure also cannot used for the demonstration of the effects.

All together the paper is valuable for presentation in A and A, and it only needs minor revisions.

Reviewer #2: Overall:

I do not understand the point of this study. The evidence is that forced air warming is highly effective at

decreasing wound infections. There is no such evidence for laminar flow. Can the authors give examples of institutions where forced air warming is not used because it "might" disturb the laminar airflow, or is the concern purely theoretical?

Abstract:

No comment

Background:

1. Use "thermoregulation" not "thermoregulatory defenses".
2. This section confirms the efficacy of forced air warming, and the dubious effect of laminar flow. So where is the basis for the "theoretical concern". The authors need to give concrete examples or I can see little justification for the study.

Methods:

1. Was the effect of human movement around the OR table considered?

Results:

1. No comment

Discussion:

1. No comment

Reviewer #3: The study, "Forced-Air Warming Does Not Worsen Air Quality in Laminar Flow Operating Rooms" by Sessler et al was designed to test the hypothesis that laminar flow performance does not deteriorate during forced-air warming. The authors studied both upper body and under patient blankets and in 2 separate laminar flow rooms at different sites. The authors demonstrated there was no difference in reduction of tracer particle concentrations between a forced-air blower set to off, ambient air, or high temperature. In addition, activation of a forced-air warming system did not interfere with the function of the laminar flow process. The manuscript was well written, the methodology explained thoroughly and the discussion and conclusions for the most part reflect the results. There are a few concerns regarding the manuscript that need to be addressed.

Major Concerns:

1. Discussion, page 15 paragraph 3 and page 16 paragraph 1 should be either modified or deleted as the correlations do not reflect the hypothesis and results of this study. The authors effectively demonstrate that forced air warming does not impair the effectiveness of laminar flow and would not prevent the laminar flow from reducing the risk of infection, if laminar flow is truly effective in reducing infection. The 2 specific paragraphs in question relate to a second but separate concern with forced air warming- that it has been postulated that forced air warmers may have the potential to increase bacterial counts at the site of surgery. The current study does not study bacterial counts, only the effect of forced air on laminar flow effectiveness. In the discussion (paragraph 3, page 15), the authors correlate their results with studies that demonstrate no increase in bacterial counts and imply that their data supports similar results. Since particles of a synthetic oil, not bacterial counts were measured, the authors should not imply that their data is consistent with studies showing no increase in bacterial counts. It is suggested that this is deleted from the discussion. Similarly paragraph 1, page 16 discusses forced air warmers as sources of contaminants, not as affecting laminar flow effectiveness. Suggest deleting this paragraph.
2. Abstract and manuscript: in the conclusion, consider deleting the part of final sentence that states "forced air remains the only??shown in randomized trials to reduce surgical site infection" as this study

does not test that statement. However the study does support that forced air warming remains an appropriate intraoperative warming method when laminar flow rooms are used.

Minor Concerns:

1. Background section, page 5 line 10. Suggest removing adjective "remarkably" before safe.
2. Methods: Figures one and two appear to be very similar and could they be combined into one figure
3. Results- do figures 1 and 2 add any information beyond the text and the data shown in table 1?
4. Abstract: in conclusion, suggest deleting the statement "-based on rigorous performance testing methods" as it was already stated in background that rigorous and objective standards were used.

Reviewer #4: Dr. Olmsted and colleagues investigated the influence of properly applied forced warm air blankets on the effectiveness of a laminar flow system. They conclude that there is no clinically or statistically significant influence of forced warm air blankets on the air quality.

The authors must be complimented with the methodological rigorousness with which they have investigated this very relevant subject.

The disturbance of laminar air flow system by a warm air blanket is a recurring point of discussion between some surgical specialists and anesthesia personnel and even is the basis of a commercial campaign for electricity based warming material. The conclusions of this study are therefore very relevant to both anesthesiologists, as well as surgical specialists.

The article in general is generally well written and easy to understand (with one exception, see below). I do not have major methodological comments or comments regarding the contents of the manuscript.

There are however a number of minor suggestions I would like to make:

(page 5)

The instructions for authors suggest an 'introduction' section, not a 'background' section.

(page 5, ln 21, Furthermore? ?factor-of-three.9,10)

I doubt that the effect on surgical site infection is causally related to forced air warming. My guess would be it is the normothermia (which is off course often maintained by forced warm air) that actually reduces the infection rates.

(page 7, ln 50, Tests were conducted?)

Purely out of personal interest, I wonder whether the operating rooms in Amersfoort and Utrecht, approximately 4000 miles away, were the closest available class 1a rooms to Cleveland, OH. Could the authors elaborate on their choice for these operating rooms?

(page 10, ln 15, The standard requires?)

Please correct and to an

(page 15, ln 9 - 28)

The statement that forced-air warming improves peri-operative outcome is not completely correct in my opinion. As suggested in the comment above: it is normothermia that improves outcome. Although I agree with the authors that almost all off the studies regarding this subject are done using forced air warming, I think the authors would agree that other measures probably achieve the same effect as long as the normothermia is the same. The fact that almost all of the studies are done with forced warm air reflects clinical practice as well as the safety and efficacy of forced warm air for maintaining normothermia.

I would like the authors to rephrase the paragraph reflecting this.

(page 15, ln 27 - 29)

I agree that forced warm air, if properly applied, is extremely safe, but would like t

(page 16, ln 32-60)

It took me several times of reading this paragraph over and over before I felt confident I understood what the authors tried to explain in this paragraph. I would recommend rephrasing this paragraph or maybe even omitting it. After all, this study is not on the bacterial contamination on the warm air blower surfaces or orifices. It is on the disturbance of laminar air flow systems.

(page 17, ln 40)

Please correct the broken bookmark/link.

(page 18, ln 6, unless?)

I would omit the remark regarding a future RCT. It weakens the message without adding anything.